IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.,	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION,	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8974

Bartle, J. November 27, 2012

Barbara Carter ("Ms. Carter" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Roy M. Carter, Ms. Carter's spouse, also has submitted derivative claims for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In June, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust he has signed in excess of 315 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 23, 1997, Dr. Evans attested in Part II of Ms. Carter's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension,

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $528,405.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist, Leo Egbujiobi, M.D., stated that claimant had mild mitral regurgitation. Dr. Egbujiobi, however, did not specify a percentage as to claimant's level of mitral regurgitation.[5] Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In July, 2005, the Trust forwarded the claim for review by David I. Silverman, M.D., one of its auditing cardiologists. In audit, Dr. Silverman concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Carter had moderate mitral regurgitation because her

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared in May, 2002 by Dr. Evans based on her December 23, 1997 echocardiogram. In this report, Dr. Evans stated that "[t]here is moderate mitral regurgitation with the mitral regurgitation [sic] jet occupying approximately 25% of the left atrial area."

echocardiogram demonstrated only physiologic mitral regurgitation.[6] In support of this conclusion, Dr. Silverman explained that "[n]o more than trace [mitral regurgitation] is seen in any view."

Based on Dr. Silverman's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Carter's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted an affidavit from Dr. Evans in which he confirmed his previous finding that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 25%. Claimant argued that the affidavit of Dr. Evans provided a reasonable medical basis to support her claim. Ms. Carter further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

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6. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane of <+ 5% RJA/LAA.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Carter's claim.

The Trust then issued a final post-audit determination, again denying Ms. Carter's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Carter's claim should be paid. On November 15, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5847 (Nov. 15, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 24, 2006, and claimant submitted a sur-reply on March 21, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Carter reasserts the arguments she made in contest; namely, that the affidavit of Dr. Evans provides a reasonable medical basis for the finding of moderate mitral regurgitation. Claimant also contends that the concept of inter-reader variability accounts for the difference between the opinion of the attesting physician and that of the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Carter contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the

RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the supplemental opinion of the attesting physician does not establish a reasonable medical basis for Ms. Carter's claim because Dr. Evans merely restates his previous finding and does not identify a sustained jet of mitral regurgitation that occupies at last 20% of the left atrial area. The Trust also notes that Dr. Evans does not address the original echocardiogram report prepared by Dr. Egbujiobi, which indicates that claimant had only mild mitral regurgitation. The Trust further contends that inter-reader variability does not establish a reasonable medical basis for the claim because Dr. Silverman specifically determined that there was no reasonable medical basis for the findings of Dr. Evans.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Carter had moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

> A small, thin and short jet of mitral regurgitation was noted in the parasternal long-axis view. Only trace mitral regurgitation was noted in the apical two chamber view with the jet found to be within 1 cm of the mitral annulus. The mitral regurgitation jet was most impressively seen in the apical four chamber view. However, this was still noted to be a thin jet that did not reach the mid portion of the left atrium in systole. This mitral regurgitation jet was noted to occur laterally within the left atrium. Visually, the degree of mitral

> regurgitation appeared to be mild in the apical four chamber view and trace in the apical two chamber view. I digitized those cardiac cycles in the apical four chamber view in which the mitral regurgitation appeared most severe. I then digitally traced and calculated the RJA and LAA. The RJA/LAA ratio was less than 8% in those views in which the mitral regurgitation jet appeared most severe. The RJA/LAA ratio never came close to approaching 20%. Most of the cardiac cycles in the apical four chamber view demonstrated RJA/LAA ratios less than 5%. I also digitized several cardiac cycles in the apical two chamber view. Once again, digital evaluation of the mitral regurgitation jet demonstrated that only trace mitral regurgitation was noted in the apical two chamber view.

After reviewing the entire show cause record, we find claimant's arguments are without merit. Claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. She does not rebut the auditing cardiologist's determination that "[n]o more than trace [mitral regurgitation] is seen in any view."[9] Nor does she challenge Dr. Vigilante's conclusion that "[t]he RJA/LAA ratio was less than 8% in those views in which the mitral regurgitation jet appeared most severe. The RJA/LAA ratio never came close to approaching 20%."[10] Neither claimant nor her attesting physician identified any particular error in the conclusions of the auditing cardiologist or the Technical Advisor. They also did

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9. For this reason as well, we reject claimant's argument that the auditing cardiologist substituted his personal opinion for the diagnosis of the attesting physician.

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

not provide an explanation for the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Carter had moderate mitral regurgitation is also misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates an RJA/LAA ratio of less than 8% and the auditing cardiologist determined that claimant had, at most, trace mitral regurgitation. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover benefits with an RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[11]

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11. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Carter's claim for Matrix Benefits and the related derivative claim submitted by her spouse.